510(k) Summary
Gaymar Industries Inc.

JAN 2 0 2011

Medi-Therm Hyper/Hypothermia System

K100585

SUBMITTER/510(K) HOLDER

Name:	Gaymar Industries Inc.
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Date Prepared:	May 7, 2010

DEVICE NAME

Proprietary Name:	Medi-Therm Hyper/Hypothermia System
Catalog Numbers:	MTA6900, MTA7900
Common/Usual Name:	Hyper/Hypothermia System
Classification Name:	Thermal Regulating System (21 CFR § 870.5900)
Product Code:	DWJ

PREDICATE DEVICES

Gaymar Industries Inc. ("Gaymar") claims substantial equivalence to:

1. Gaymar Industries Inc. Medi-Therm System MTA5900 (K912051)
2. MedCool Inc. RapidCool™ Patient Temperature Management System, (K070112)
3. Medivance ArcticSun Temperature Management System (K071341)
4. M.T.R.E. Advanced Technology Ltd. CritiCool System (K083662)
5. M.T.R.E. Advanced Technology Ltd. Allon 2001 System (K003349)

DEVICE DESCRIPTION

The Gaymar Medi-Therm device provides a means of regulating patient temperature by supplying temperature-controlled water through a connector hose to accessory Gaymar Hyper/Hypothermia blanket(s)/body wrap(s). The blanket/body wrap provides an interface for heating or cooling the patient. Accessory YSI 400 series patient probe interfaces between the Medi-Therm and patient to sense patient temperature, which is displayed on the device's control panel. The Medi-Therm device controls output water temperature by mixing hot and cold water

using hot and cold solenoid valves under microprocessor control. The device includes a circulating pump, heater and refrigeration system.

The Medi-Therm controller, connector hose, blanket/body wrap and patient probe comprise the Medi-Therm Hyper/Hypothermia System.

INTENDED USE

The Medi-Therm is intended for use in supplying warm or cold water at controlled temperatures via water circulating blankets or body wraps for the application of regulating patient temperature in situations where a physician determines that temperature therapy is necessary and desirable.

Indications for use for the Medi-Therm thermal regulating system include:

a. To maintain pre-set body temperature as determined by the physician
b. To maintain normal body temperature during surgical procedures
c. For use in all hospital areas including invasive and coronary care units, in operating, recovery and emergency rooms, in burn units and on medical/surgical floors
d. This system can be used with adult and pediatric patients
e. Monitoring and controlling patient temperature
f. Temperature reduction in patients where clinically indicated, e.g. in hyperthermic patients

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Substantial equivalence is based on five predicate devices. All above referenced predicates are thermal regulating systems as defined in 21 CFR § 870.5900.

Like the Medi-Therm, all predicate devices utilize a controller incorporating a water circulation pump, hose sets, a disposable non-sterile body surface contact appliance and a means to monitor the patient temperature. The devices all require a physician's prescription for use. The external anatomical sites for the patient contact appliance are similar for all devices – trunk and extremities. The RapidCool additionally uses neck and head patient contact appliances. All device patient contact appliances are applied on, around and/or under the patient where the thermal transfer is dependent upon patient contact.

The Medi-Therm is equivalent in operational characteristics to the predicate devices in that the control units all use microprocessors to circulate temperature–controlled water at similar non-adjustable flow rates through hose sets to a patient contact pad/blanket/garment. Flow rates however, will be determined by pad/blanket/garment size and quantity connected to the devices. The physician determines the size and quantity of pad/blanket/garment to be used.

In each device's Automatic Mode, patient temperature is monitored and controlled through the use of commercially available YSI 400 series probes connected between the controller and patient. The physician selects a therapeutic temperature and the device user sets the desired patient temperature for hyper/hypothermia condition via the controller interface. Each device will channel the temperature controlled water to the patient contact pad/blanket/garment to achieve and maintain the controller setting for patient temperature. The Medi-Therm Automatic mode temperature is in the range of 30 – 41°C, the same range as supported by the predicate devices. Additionally, the Medi-Therm and Arctic Sun have Manual Modes where a user can set water temperature (not patient temperature) in the range of 4 – 42°C to be circulated to the patient contact pad/blanket/garment.

The Medi-Therm includes additional temperature control options within the Automatic Mode. The user can select either Gradual, Moderate or Rapid cooling modes for the MTA6900. The user can select either Gradual, Moderate or Rapid cooling and warming modes for the MTA7900. These pre-set temperature control modes are within the previously cleared temperature range for the device.

All of the predicate devices' cooling sources are either water/air heat exchanger, thermoelectric or typical refrigeration compressor. The heating sources are electrical heater elements ranging from 500 – 800W. The Medi-Therm, CritiCool and Arctic Sun include a power on self test (POST) and safety alarms for water level, interrupted water flow, patient probe anomalies including patient temperature and open/short circuit, and high water temperature. The redundancy of high water temperature protective circuits is to the tertiary level for the Medi-Therm and Allon 2001 and at least duplicative for the Arctic Sun device. The primary high water temperature for the Medi-Therm is software controlled with bimetallic thermostats for the secondary and tertiary levels.

The patient contact pad/blanket/garment operating water pressure is atmospheric for the Medi-Therm, RapidCool, CritiCool and Allon 2001and Medi-Therm predicates. Whereas, the Arctic Sun's operating pressure is sub-atmospheric.

Bench testing was conducted to confirm the MTA6900 and MTA7900 and their disposable accessories operate as described in this submission and therefore are as safe and effective as the predicate devices to which it claims substantial equivalence. Bench testing included:

- Temperature Control Performance
- Temperature Stability and Flow
- Biocompatibility (ISO 10993-5; ISO10993-10; 16 CFR 1500)
- Ship Testing (ISTA 1A)

The MTA6900 and MTA7900 controller comply with the following standards:

- IEC/EN60601-1-2 – Medical Electrical Equipment, Pat 1: General Requirements for Safety, Collateral Standard: Electromagnetic Compatibility Requirements and Tests

- CISPR 11 / EN 55011, Limits and Methods of Measurements of Radio Disturbance Characteristics of Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment
- UL 416 – Refrigerated Medical Equipment

Results of the bench testing concludes that the design, operational and technical characteristics of the Medi-Therm Hyper/Hypothermia System is substantially equivalent to and as safe and effective as that of the predicate devices.

The Medi-Therm Hyper/Hypothermia Systems' intended uses are substantially supported by the previously cleared predicate devices. The Medi-Therm Hyper/Hypothermia Systems' indication for use statement includes all the same indications as the previously cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Gaymar Industries, Inc.
c/o Mr. Brian L. Orwat
10 Centre Dr.
Orchard Park, NY 14127

JAN 20 2011

Re: K100585
Trade/Device Name: Medi-Therm Hyper/Hypothermia System, MTA6900 and MTA7900
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: II
Product Code: DWJ
Dated: January 14, 2011
Received: January 18, 2011

Dear Mr. Orwat:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K100585

Device Name: Medi-Therm Hyper/Hypothermia System

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Prescription Use __X__ AND/OR Over-The-Counter Use __
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vickers

(Division Sign-Off)
Division of Cardiovascular Devices

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